

Transmissible Spongiform Encephalopathies Advisory Committee  
October 25, 2001  
Statement from the New York Blood Center

September 11<sup>th</sup> changed our world. At least temporarily, it also altered the landscape of blood donor recruitment and blood supply. Suddenly we went from suffering the perils of chronic blood shortages to dealing with the equally problematic issues of acute oversupply and system overload. Relative to the horizon of new blood donor deferrals released as draft guidance from FDA, we have experienced some setbacks in implementing the planned initiatives as we suddenly had other priorities related to the World Trade Center attack. The setbacks are related to delays in dealing with our European partners for planning the phase out of Euroblood, postponements of meetings with the military, and delays in dealing with alternative US suppliers. We have now begun to address these initiatives again.

As a review, we stand to lose approximately 210,000 red cell units from the NYBC effective supply as combination of Euroblood (180,000, counting the type mix effect) and 30,000 of our own collections – a total of over 25% of the areas supply. Pending further discussion with the Europeans and the publishing of final guidance, we now see phasing out approximately half of the European supply, at the end of May and the remainder at the end of October 2002. Our own donor losses from pan-European deferrals will be absorbed in October as well. The supply gaps will be made up by a combination of increasing our own collections and purchase of red cells from ABC centers, BCA and American Red Cross. These purchasing arrangements are being finalized. We expect that the relative contributions from collections and purchases will be about equal up through the end of October. After October 2002, the contribution from NYBC collections will continue to rise as a percentage of the total supply.

We are hopeful that the surge of new blood donors will add to the overall donor base of our collections. We now have active programs in place to engage the thousands of donors who were asked to defer donation during the disaster or who were first time donors that we actually collected. However with our optimism and with the current oversupply, there are warnings that the supply may be less stable than when we were dealing only with chronic shortages. Consistently, surges or massive appeals are followed by proportional troughs of donations that can lead to shortages. Furthermore, massive outdated and disposal of red cells from the overcollections following the attack will become public. The reaction of the donor base is unpredictable and must be carefully managed in order to recognize the educational opportunity regarding the perishable nature of blood. Whereas we all would like to believe that blood shortages will never recur after recent events, realistically we feel the supply is now even less stable and unpredictable than before September 11.

Upon review of the draft guidance, we also have concerns about the public implications and the management of public perception that should be addressed. Our donor group organizations as well as our hospital customers have expressed these concerns. They are related to the underlying principle of geographic deferrals. Specifically, as BSE is identified in other parts of the world or in the US, is there a plan to extend this principle and how far will this mechanism be extended? Will the millions of US citizens who travel abroad be warned of the risk of transfusion in BSE countries? And finally, does the public health benefit warrant the exclusion of 15 million Americans and 550 million Europeans from US blood donor eligibility? These questions and others are concerns from the public as well as the transfusion medicine community and will not be answered easily or today. However, we hope they are issues that will be integrated into the future thinking and actions of the committee and FDA as guardians of blood safety.

As a vanguard blood care organization we remain committed to blood safety and the efforts of FDA and the committee. We assure you that we are working diligently to manage this new horizon. However, we hope you recognize the new dynamics introduced the nation's war on terrorism and how the priorities of the public and the blood care system continue to evolve from day to day.